REMARKS

This Amendment is submitted in response to the Official Action dated 5 July 2011. Claims 1, 8, 10 and 14 are amended. Claims 6, 7 and 9 were previously canceled and claims 17-21 were withdrawn. Claims 1-5 and 8, and 10-16 remain pending for consideration in the application. The Examiner is respectfully requested to consider the following.

Claim 1 is not indefinite under 35 U.S.C. 112, second paragraph.

The Examiner contends that the limitation "said channel" in Claim 1 at line 18 lacks antecedent basis. Applicant disagrees. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. Energizer Holdings Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006). In this case the claim recites "an open-ended channel" and then refers back to "*said open-ended channel*…wherein said portion is placed in direct contact at each open end of *said channel.*" The open-ended channel provides ample antecedent for "each open end of *said channel*" and the scope of claim 1 would be reasonably ascertainable under Ex parte Porter, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid").

Claims 1-5, 8, 10-12, 14, & 16 are not anticipated under 35 U.S.C. 103(a) over U.S. 5,096,669 to Lauks et al. ("Lauks") in view of U.S. 6,379,929 to Burns as evidenced by U.S. 4,854,170 to Brimhall.

According to the Examiner, Lauks teaches each and every element of independent claims 1, 8, 10 and 14 except an ultrasonic analyzer and a channel passing through the elongate body from one external surface to another external surface wherein a portion of the fluid is placed in direct contact at each open end of the channel with a sensing surface. However, the Examiner contends that ultrasonic analyzers are known (as evidenced by Brimhall) and that Burns teaches in Figure 3A a device with channels passing through an elongated body from one external surface to another external surface (openings 20, 30 and 50). The Examiner concludes that it therefore would have been obvious to one of ordinary skill to have Lauks' cavity 18 passing

through the elongated body from one external surface to another external surface "for detection means outside of the body."

As explained previously, Lauks measures only the electrochemical properties of an internally contained sample by an electric sensing array 66 built right into the body. This enables the disposable to take the necessary measurements and yet keep the sample completely sealed inside. Similarly, Burns is an integrated DNA analysis microchip that uses electronic sensors built right into the chip body. This likewise enables the chip to take the necessary measurements of the sample and yet keep the sample completely inside the chip. Neither of these references provide any means for bringing an external sensor, acoustic or otherwise, into direct sealed contact with a blood sample still contained within the disposable. This is because neither reference has to as their electrical sensors are sealed inside the disposable.

Nevertheless, the Examiner suggests that one skilled in the art would have been motivated to combine the open channels of Burns into the disposable of Lauk in order to expose the liquid to "detection means outside of the body." Applicant maintains that the rejections fails to state a *prima facie* case of obviousness because the Examiner's proposed combination would change the principle of operation of Lauks and/or Burns inasmuch as both have sensors built into the body, and neither are designed to operate with an external sensor. *See* MPEP § 2143.01(VI). Consequently, the teachings of these two references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 813, 123 USPQ 349 (CCPA 1959) (the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." Applicant also maintains that the rejection fails to state a *prima facie* case of obviousness because the proposed modification would render Lauks entirely unsatisfactory for its intended purpose. *See* MPEP § 2143.01(V). Lauks positions a pouch 60 of calibrant fluid inside the chamber of its testing region in order to calibrate the sensors prior to measurement by puncturing the pouch to release the fluid. If the disposable Lauks were provided with channels open to its external surface as in the Examiner's suggested combination with Burns, the calibrant fluid would simply leak and escape thereby rendering Lauks entirely unusable. Consequently there is no suggestion or motivation to make the proposed modification as such would render the combination unsuitable for its intended

purpose. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Lauks, in fact, relies the fact that its channel system is sealed from the outside in order to achieve its result.

Even if the Examiner's asserted combination were proper, it still fails to recite all of the limitations of independent claims 1, 8, 10 and 14. Each of these claims requires a testing region for containing fluid during testing inside an ultrasonic analyzer, the testing region being an open-ended channel perpendicular to the capillary tube and passing through the thin elongate body from one external surface to another external surface. The Examiner equates this to the cavity 18 of Lauk's and says that cavity 18 is "open" in respect to passing over sensors when actuated column with reference to the specification at col.10 lines 3-10, figure 3, column 5 lines 39-60, column 10 lines 3-20. Each of the Examiner's citations to the specification describe how a calibrant pouch fits inside cavity 18 and is pierced to release the calibrant to the sensors. Cavity 18 may indeed be "open" to sensors 60 to allow the internally contained calibrant to reach the sensors, but this is not what is claimed or in any way equivalent to what is claimed. The present claims recite an open-ended channel *perpendicular to said capillary tube* and *passing through said thin elongate body from one external surface thereof to another*. Being "open" in respect to passing over sensors when actuated is not reasonably equivalent to an open-ended channel perpendicular to said capillary tube and passing through said thin elongate body from one external surface thereof to another. Consequently, the Examiner's rejection is respectfully traversed as simply failing to recite that for which the Examiner credits it or as an unreasonably broad and impermissible interpretation of the claims. See MPEP § 2111.01, Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.)

Even given the Examiner's loose interpretation of Applicant's claim language the cited prior art combination is simply not obvious and Applicant traverse the Examiner's §103 rejection on its merits. Granted that Brimhall discloses an analyzer that uses ultrasonic waves, but it is completely different in principal and operation from the present invention. Brimhall submits a blood sample in a sealed chamber to high-power ultrasound creating a standing wave in the fluid volume. Because red cells are denser than blood plasma the high-power ultrasound forcibly separates the red blood cells ("RBCs") into bands corresponding to the nodes of the standing wave. Once the RBCs are in bands the relative width of the bands are measured to determine the

percentage of RBCs in the blood (the hematocrit). The technique is very similar to the age-old technique of centrifuging the blood to forces the separation of components and then measures the volume of blood cells as compared to the total volume by direct optical measurements (i.e., visually). Applicant's invention employs ultrasound in a completely different manner, transmitting and receiving ultrasound as a purely acoustic signal through the blood sample to determine blood properties based on ultrasonic characteristics such as transmission latency or backscatter.

The improvement in Applicant's invention is not only that it accepts a small volume of blood (<.05 ml), but also that it is able to make an accurate ultrasonic measurement on such a small volume. Applicant discovered that an accurate ultrasonic measurement is not possible if the ultrasound is retarded/damped by passing through plastic walls to enter a sealed chamber (as Brimhall's chamber is), or if there are air bubbles in the sample. To address these issues Applicant invented a disposable that, among other things, mates with an *external acoustic* sensor in direct sealed contact with the blood sample while the blood is still contained within the disposable. This had never before been accomplished, and none of the Examiner's cited references is capable, individually or in combination, of doing this. The Examiner glosses over this fact, stating that Burns may be connected to a detection means (column 11 lines 1-10), and so it would have been "obvious to one of ordinary skill to have channel 18 passing through an elongated body from one external surface to another external surface for detection means outside of the body." However, the Burns detection means referred to is a microarray *inside* the disposable body, not outside, and so exactly how the Examiner gets to that external sensor is unclear from her rejection. None of the cited references mates with an *external acoustic* sensor in direct sealed contact with the blood sample while the blood is still contained within the disposable. As the Supreme Court stated in KSR International Co. v. Teleflex Inc., 550 U.S. 398, 420, 82 USPQ2d 1385, 1396 (2007), the key to supporting an obviousness rejection is the clear articulation of the reason(s) why the claimed invention would have been obvious. (See MPEP §2142.) It is pure hindsight to adjudge Applicant's effort as an obvious combination of piecemeal features chosen from disparate prior art references, and to suggest that said features can be combined for reasons entirely unrelated to Applicant's purpose. Such piecemeal reconstruction ignores the compound problem faced by Appellant and the synergistic solution provided.

Additionally, even if the Examiner finds all of the foregoing arguments unpersuasive, Applicant has further amended each of claims 1, 8, 10 and 14 to emphasize the patentable structure and prevent further loose and unreasonably broad interpretation of the claim language. All said claims now require "an open-ended *cylindrical* channel passing through said thin elongate body perpendicular to said capillary tube from one external surface of said body to another, thereby defining *a circular aperture* in said thin elongate body *adapted to be sealed off by an external sensor of said portable ultrasonic analyzer when inserted therein such that at least a portion of a blood sample is sealed within the cylindrical channel and therein directly exposed to said external sensor*". Lauk's testing cavity 18b is not cylindrical, and does not pass through so as to define a circular aperture adapted to be sealed by external sensors walls. Indeed, none of the prior art references relied upon provide any means for bringing an external acoustic sensor into direct contact with a blood sample while the blood is still contained within a disposable device and none of the cited references teach or suggest the foregoing limitations.

Claims 2-5, 11-13 and 15-16 depend from claim 1 and incorporate the same patentable limitations.

Claims 6, 7 and 9 are canceled.

Claim 13 is not obvious under 35 U.S.C. 103(a) as being unpatentable over Lauks as evidenced by U.S. Patent 6,759,007 to Westberg et al.

Claim 13 depends from claim 10 and incorporate the same patentable limitations.

Claim 15 is not obvious under 35 U.S.C. 103(a) as being unpatentable over Lauks in view of U.S. Patent 5,257,984 to Kelley.

Claim 15 depends from claim 14 and incorporate the same patentable limitations.

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In light of the above amendments and remarks, the claims are believed to avoid all the rejections set forth in the Official Action. Thus, all of claims 1-5, 8 and 10 -16 are believed to be in condition for allowance. A Notice to this effect is respectfully requested.

Respectfully submitted,

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Date October 5, 2011